JUN 2 9 2007

DFine
19450 Stevens Creek Blvd., Suite 100
Cupertino, California 95014

Premarket Notification [510(K)] Summary
(per 21 CFR 807.92)

510(k) number K070351

1. Submitted by:

DFine, Inc.
3047 Orchard Parkway
San Jose, CA 95134

Contact Person: Robert D. Poser, D.V.M.
Vice-President, Scientific and Medical Affairs
Telephone: 408-321-9999 ext 224
Facsimile: 408-321-9402

Date Prepared: **June 28, 2007**

2. Device Name

Trade/Proprietary Name: SPACE 360 Delivery System
Common/Usual Name: Polymethylmethacrylate Bone Cement
Classification Name: Polymethylmethacrylate Bone Cement, Cement Dispenser

3. Predicate Device:

The SPACE 360 Delivery System is substantially equivalent to the Equestra, cleared under 510(k) K040483 by Medtronic Sofamor Danek, the Confidence Fenestrated Introducer Needle cleared under 510(k) K063067by Disc-O-Tech, the Disc-O-Tech Cementer Injector classified under Product Code KIH and the ArthroCare System, cleared under 510(k) K040338 by ArthoCare.

4. Intended use of the device

The SPACE 360 Delivery System is intended for percutaneous delivery of SPACE CpsXL Bone Cement in vertebroplasty or kyphoplasty procedures in the treatment of pathological fractures of the vertebrae. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

5. Description of the Device

The SPACE 360 Delivery System consists of a reusable controller and disposable, single-use components, including a delivery cannula and stylet, a hydraulic assembly and bone cement syringe, and control cables.

6. Testing and Conclusion

Mechanical performance and safety testing demonstrates that the SPACE 360 Delivery System meets its performance requirements to support its use as a bone cement delivery system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

DFine, Inc.
c/o Robert D. Poser, DVM
Vice President, Scientific and Medical Affairs
3047 Orchard Parkway
San Jose, CA 95134

Re: K070351
Trade/Device Name: SPACE 360 Delivery System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: NDN, KIH
Dated: May 12, 2007
Received: May 14, 2007

Dear Dr. Poser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K070351

Device Name: SPACE 360 Delivery System

Indications for Use:

The SPACE 360 Delivery System is intended for percutaneous delivery of SPACE CpsXL Bone Cement in vertebroplasty or kyphoplasty procedures in the treatment of pathological fractures of the vertebrae. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070351